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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,606	09/07/1999	ANDREW D. MURDIN	1038-971-MIS	8817

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/31/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/391,606	Murdin et al.
Examiner	**Art Unit**
Shin-Lin Chen	1632

-- Th MAILING DATE of this communication appears on th cover she t with the correspondenc address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 23, 2002

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the applica

4a) Of the above, claim(s) 3 and 8 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, 4-7, and 9-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election of group I, claims 1, 2, 4-7 and 9-23, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MEP. § 818.03(a)).

2. Claims 3 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 10.

Applicants' amendment filed 8-23-02 has been entered. Claims 21-23 have been canceled in the amendment filed 12-5-01. Claims 14 and 16 have been amended. Claims 1-20 are pending and claims 1, 2, 4-7 and 9-20 are under consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 and 11 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and is repeated for the reasons set forth in the preceding

Official action mailed 2-22-02 (paper No. 15). Applicant's arguments filed 8-23-02 have been fully considered but they are not persuasive.

Applicants refer to the specification page 9 lines 23 (amendment, p. 2). This is not found persuasive because the specification only specifically define the "76 kDa protein" of Chlamydia and said 76 kDa protein has two open reading frames encoding a 35 kDa protein and a 60 kDa protein. However, the specification fails to specifically define "**a** 76 kDa protein having a molecular size of about 35 kDa" or "**a** 76 kDa protein having a molecular size of about 60 kDa". Changing "a 76 kDa protein" to "the 76 kDa protein" would be remedial.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 2, 4-7, 9-17, 19 and 20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and is repeated for the reasons set forth in the preceding Official action mailed 2-22-02 (paper No. 15). Applicant's arguments filed 8-23-02 have been fully considered but they are not persuasive.

Applicants argue that the specification is addressed to a person skilled in the art, the sequences were known in the art and it is not necessary to have personal possession of such sequences (amendment, p. 3). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-22-02 (paper No. 15). The scope of the claim includes nucleotide sequences encoding a genus of numerous structural variants of the disclosed MOMP or 76 kDa protein, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The claimed nucleotide sequences encompass unknown and unidentified nucleotide sequences encoding MOMP or 76 kDa protein derived from various species and strains of *Chlamydia*. The specification fails to provide the nucleotide sequences encoding those MOMP or 76 kDa proteins derived from various species and strains of *Chlamydia*. Thus, the limited information as disclosed is not sufficient to reasonably convey to one skilled in the art that applicants were in possession of the nucleotide sequences encoding MOMP or 76 kDa proteins derived from various species and strains of *Chlamydia* for the immunogenic composition as claimed.

7. Claims 1, 2, 4-7 and 9-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of a plasmid encoding the disclosed MOMP and a plasmid encoding the disclosed 76 kDa of *C. Pneumoniae* before challenge of *C. Pneumoniae*, and induction of a protective immune response against sublethal *C. Pneumoniae* lung infection in mice, does not reasonably provide enablement for an immunogenic composition

comprising a vector encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for the protection of any host, including human, against a particular disease, such as any chlamydial infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 2-22-02 (paper No. 15). Applicant's arguments filed 8-23-02 have been fully considered but they are not persuasive.

Applicants argue that the specification discloses vectors pCAMOMP and pCA76kDa are used to provide protection against C. Pneumoniae lung infection in mice and the claims are not directed to a method of immunization (amendment, p. 4). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-22-02 (paper No. 15). The claims are directed to an **immunogenic** composition for *in vivo* administration to a host. Although the claim are not directed to a method of immunization, the claimed immunogenic composition must have a use for one skilled in the art at the time of the invention. The use of the **immunogenic** composition is to stimulate immune response in a host so as to immunize the host or provide therapeutic effects against a particular disease, such as Chlamydial infection, in the host in light of the specification (see specification, p. 9 lines 7-11). Therefore, the claims read on gene therapy *in vivo* and the claimed immunogenic composition must have a use for stimulating immune response in a host so as to immunize the host or provide therapeutic effects against a particular disease, such as Chlamydial infection, in the host. The claims read on using nucleotide

sequence encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for *in vivo* administration of any host, including human, mammals, birds, reptiles, fishes etc., to protect the host against a particular disease. The specification only discloses the use of a vector (pCAMOMP) expressing MOMP and a vector (pCA76kDa) expressing a 76 kDa protein of a strain of *C. Pneumoniae* as disclosed in the present application for protection against *C. Pneumoniae* lung infection in mice. The specification fails to provide adequate guidance and evidence for an immunogenic composition containing nucleotide sequences encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for *in vivo* administration of any host, including human, mammals, birds, reptiles, fishes etc., to protect the host against a particular disease, such as a Chlamydial infection, other than using the disclosed pCAMOMP and pCA76kDa to protect against *C. Pneumoniae* lung infection.

Applicants argue that the specification does not claim to provide protection against other than Chlamydial infections (amendment, p. 4). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 2-22-02 (paper No. 15) and the reasons set forth above in previous paragraph. The claims do not specify any particular Chlamydial infection or particular disease. The broadest reasonable interpretation of the claims as a whole encompasses using the immunogenic composition containing nucleotide sequences encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for *in vivo* administration of any host, including human, mammals, birds, reptiles, fishes etc., to protect the host against any Chlamydial infection or any disease other than the Chlamydial infection. It is

not necessary that the antigen of Chlamydia can only be used to prevent Chlamydial infection because if the antigen of Chlamydia is involved in cell proliferation, said antigen may be used to treat diseases associated with cell proliferation. Thus, the claims remain rejected under 35 U.S.C. 112 first paragraph.

Conclusion

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.